

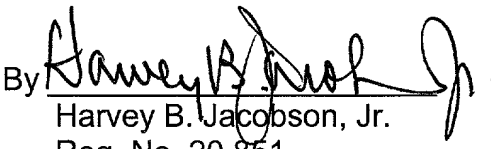
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED / ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER P67157US0
		US APPLICATION NO. (If known, see 37 CFR 1.5) 09/926293
INTERNATIONAL APPLICATION NO. PCT/DK00/00168	INTERNATIONAL FILING DATE 6 April 2000	PRIORITY DATE CLAIMED 7 April 1999
TITLE OF INVENTION A PRESSURE RELIEVING DRESSING		
APPLICANT(S) FOR DO/EO/US Truels Sterm LARSEN -and- Henrik OLSEN		

Applicant herein submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for Internatl. Preliminary Examination was made by the 19th month from earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the Internatl. Preliminary Examination report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
 - International Search Report – EPO
 - PCT Request Form
 - PCT/IB/304 Form
 - First Page of Publication
 - International Preliminary Examination Report – with Annexes

US APPLICATION NO. (if known, see 37 CFR 1.5) <div style="font-size: 1.5em; font-weight: bold;">09/926293</div>		INTERNATIONAL APPLICATION NO. <div style="font-weight: bold;">PCT/DK00/00168</div>		ATTORNEY'S DOCKET NUMBER <div style="font-weight: bold;">P67157US0</div>			
17. <input checked="" type="checkbox"/> The following fees are submitted: Basic National Fee (37 CFR 1.492(a)(1)-(5)): Internatl. prelim. examination fee paid to USPTO (37 CFR 1.492 (a) (1)) . . \$710.00 No international preliminary examination fee paid to USPTO (37 CFR 1.492 (a) (2)) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) . . \$740.00 Neither international preliminary examination fee (37 CFR 1.492 (a) (3)) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO) \$1040.00 International preliminary examination fee paid to USPTO (37 CFR 1.492 (a) (4)) and all claims satisfied provisions of PCT Article 33(2)-(4) \$100.00 Search Report prepared by the EPO or JPO (37 CFR 1.492 (a) (5)) \$890.00 <div style="text-align: right; font-weight: bold;">ENTER APPROPRIATE BASIC FEE AMOUNT =</div>				CALCULATIONS \$ 890.00		PTO USE ONLY	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$			
Claims	Number Filed	Number Extra	Rate				
Total Claims	12 - 20 =	-0-	x \$18.00	\$			
Independent Claims	1 - 3 =	-0-	x \$84.00	\$			
Multiple Dependent Claim(s) (if applicable)			+ \$280.00	\$			
TOTAL OF ABOVE CALCULATIONS =				\$ 890.00			
Reduction by 1/2 for filing by small entity , if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				\$			
SUBTOTAL =				\$ 890.00			
Processing fee of \$130 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f))				\$			
TOTAL NATIONAL FEE =				\$ 890.00			
Fee of \$40.00 for recording the enclosed assignment (37 CFR 1.21(h)). Assignment must be accompanied by appropriate cover sheet (37 CFR 3.28, 3.31).				\$			
TOTAL FEES ENCLOSED =				\$ 40.00			
				Amt. to be refunded:		\$	
				Amt. charged:		\$	
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>930.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. <u>06-1358</u> in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge my account any additional fees set forth in §1.492 during the pendency of this application, or credit any overpayment to Deposit Account No. <u>06-1358</u> . A duplicate copy of this sheet is enclosed.							
SEND ALL CORRESPONDENCE TO: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> JACOBSON HOLMAN PLLC 400 7th Street, N.W., Suite 600 Washington, DC 20004 202-638-6666 CUSTOMER NUMBER: 00136 </div> <div style="width: 45%; text-align: right;"> By  Harvey B. Jacobson, Jr. Reg. No. 20,851 </div> </div>							

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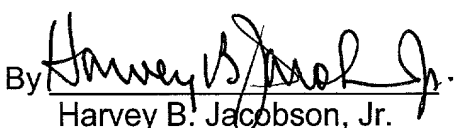
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By  Harvey B. Jacobson, Jr. Reg. No. 20,851					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Truels Stern LARSEN et al.

Serial No.: New

Filing Date:

For: A PRESSURE RELIEVING DRESSING

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified application as follows:

IN THE SPECIFICATION

On page 1, immediately following the title, please insert the following sentence: --This is a nationalization of PCT/DK00/00168 filed April 6, 2000 and published in English.--

Please incorporate the new Abstract of the Disclosure into the specification, submitted herewith on a separate sheet.

IN THE CLAIMS

Please amend claims 3, 5 through 12 as follows:

3. (amended) A dressing according to claim 1, characterised in that the pressure distributing element (2) is an elastomer.

5. (amended) A dressing according to claim 1, characterised in that the absorbent element (1) comprises a hydrophilic foam, such as

polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinylpyrrolidone gels or hydrocolloids.

6. (amended) A dressing according to claim 1, characterised in that the surface opposite the skin-contacting surface of the dressing is covered by a top layer (3).

7. (amended) A dressing according to claim 1, characterised in that the absorbent element (1) extends through the pressure distributing element (2).

8. (amended) A dressing according to claim 1, characterised in that the absorbent element (1) extend partly through the pressure distributing element (2).

9. (amended) A dressing according to claim 1, characterised in that the pressure redistributing material (2) comprises one or more indentations (9).

10. (amended) A dressing according to claim 1, characterised in that the dressing comprises a pressure indicator.

11. (amended) A dressing according to claim 1, characterised in that the absorbent element (1) comprises a pharmaceutical or antimicrobial agent.

12. (amended) A dressing according to claim 1, characterised in that the surface of the dressing to be brought in contact with the skin shows adhesive properties.

REMARKS

The foregoing Preliminary Amendment is requested in order to delete the multiple dependent claims and avoid paying the multiple dependent claims fee.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Early action on the merits is respectfully requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By Harvey B. Jacobson, Jr.
Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666

Atty. Docket: P67157US0
Date: October 9, 2001
HBJ/cmf

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

3. (amended) A dressing according to claim 1 [or 2], characterised in that the pressure distributing element (2) is an elastomer.

5. (amended) A dressing according to claim 1 [any of claims 1-4], characterised in that the absorbent element (1) comprises a hydrophilic foam, such as polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinylpyrrolidone gels or hydrocolloids.

6. (amended) A dressing according to claim 1 [any of claims 1-5], characterised in that the surface opposite the skin-contacting surface of the dressing is covered by a top layer (3).

7. (amended) A dressing according to claim 1 [any of claims 1-6], characterised in that the absorbent element (1) extends through the pressure distributing element (2).

8. (amended) A dressing according to claim 1 [any of claims 1-6], characterised in that the absorbent element (1) extend partly through the pressure distributing element (2).

9. (amended) A dressing according to claim 1 [any of claims 1-8], characterised in that the pressure redistributing material (2) comprises one or more indentations (9).

10. (amended) A dressing according to claim 1 [any of claims 1-9], characterised in that the dressing comprises a pressure indicator.

11. (amended) A dressing according to claim 1 [any of claims 1-10], characterised in that the absorbent element (1) comprises a pharmaceutical or antimicrobial agent.

12. (amended) A dressing according to claim 1 [any of claims 1-11], characterised in that the surface of the dressing to be brought in contact with the skin shows adhesive properties.

09/926293

1

TITLE

A pressure relieving dressing

FIELD OF THE INVENTION

The present invention relates to a pressure relieving dressing used for prophylaxis or treatment of ulcers as well as for protection of fragile skin.

BACKGROUND OF THE INVENTION

Many people, especially diabetics, who suffers from long term complications such as ischaemia and neuropathy or patients confined to their bed are known to develop ulcers on foot, hip or sacrum. Foot ulcers are usually located on the plantar or on the side or dorsum of the foot. Foot ulcers are induced by changes in bone structure, which can lead to protruding prominences and reduced thickness of the subcutaneous layer that ensures distribution and relief of the pressure applied to the foot.

The development of foot ulcers are i.e. dependent on a combination of etiology and the induction of pressure. There are essentially two mechanical inducers for pressure sore development, the stress of permanent (static) pressure and the stress of short term (dynamic) pressure.

The permanent or static pressure is when exertion of pressure over a long period (hours typically) is leading to the risk of collapse of veins and arteries. The collapse of these blood vessels may lead to ischemia e.g. lack of oxygen and nutrition and a build up of waste materials. These events may eventually lead to development of ulcers. The tendency is the longer period of pressure induction, the lower pressure is critical and may cause damage.

Short term or dynamic pressure impact is in the form of repetitive mechanical stress. This occurs e.g. when walking, where a typical pre-stage to ulceration is callus build-up. This type of ulceration may be compared to benign sanguinous blister formation. Critical pressure level of this type of pressure impact is much higher than in the case of a long time pressure load.

Dressings designed to manage wound healing and exudate are well known in the art. However, they do not take into account the effects of the pressure stress.

From International Patent application No. WO 91/01706 A1 (Smith & Nephew) is known a polymeric foam absorbent dressing for exudate handling in wound
5 healing. No pressure relief/distribution properties are mentioned. This dressing comprises a foam material all over the surface. Since this open cell foam is designed to allow transportation of exudate, it has inadequate strength towards pressure, and will be compressed or collapse when worn on a foot.

WO 99/01166 A1 (Coloplast A/S) discloses a non-fibrous polysaccharide wound
10 dressing capable of handling wound exudate by gelling properties. This material is very soft and gentle towards the ulcer. However, it has inadequate strength towards mechanical pressure and will collapse if pressure is applied.

Examples of pressure reducing/distributing/shock-lowering orthopaedic materials and products are also known:

15 In international Patent application No. WO 90/09746 A1 (Bernard, M.) is disclosed a composite inner sole for sports shoes, comprising a shock absorbing layer. No wound healing or exudate absorbing properties are mentioned.

US Patent No. 5 488 786 (Ratay, E.J.) discloses a highly resilient insole,
designed to cover the whole sole of the shoe i.e. the whole plantar surface of the
20 foot. No wound healing or exudate absorbing properties are mentioned.

Only few examples of a combining the two said properties are known:

From DE patent application No. 35 39 533 (Liedtke) is known a foam dressing.
The dressing comprises a foam body, the non-skin-contacting surface optionally
being covered with a film and the outer periphery of the skin-contacting edge
25 covered with an adhesive. The foam serves both as a pressure reducing and
distributing element and as an absorbent element. Between the

adhesive-covered edge and the non-adhesive central part is a groove in the foam, as well as more grooves or indentations may appear in the central part. These grooves are made to enhance the flexibility of the dressing. The dressing is made of a single piece of foam, and the only barriers to control the wound exudate is the top film and the adhesive, leaving a severe risk of maceration when used on exuding wounds. In one embodiment of the invention, the dressing comprises a slit in the foam defining a lid to be opened and an absorbing pad may be inserted over the wound. However, this construction with a slit may give rise to problems with leakage.

- 10 GB patent No. 842 847 (Scholl) discloses a corn dressing, comprising a foam ring, serving as a pressure distributing part and a thinner central part with a napped inner side having a shock absorbing/cushioning effect. In the cavity between the central part and the skin/treated area a pad with medication may be placed. The reference is silent with respect to wound treatment as well as use of
15 absorber, on the contrary, the device is donating medication to the treated site.

- International Patent application No. WO 93/01777 A1 (Malloul, L.) discloses a dressing for sutured wounds. Said dressing has a foamed shock-absorbing element or cushion layer on both sides of the wound, protecting the wound from impact or pressure, and an area spaced apart from the wound with a pad right
20 over the wound. The dressing only copes with dynamic pressure in the form of sudden impacts, and is silent with respect to static pressure.

- European Patent No. EP 0 164 319 (Coloplast A/S) discloses a wound dressing of the hydrocolloid type with a pressure relief system of foam. The pressure is distributed through the foam in order to relieve the pressure on the ulcer. The
25 dressing offers a possibility to adapt a specific relief area corresponding to the size of the ulcer, rendering it possible to transfer the pressure from the wound site to the surrounding healthy tissue. The pressure relief is described as having static pressure relieving properties, not dynamic pressure/shock relieving properties.

Diabetic patients are often suffering from neuropathy, rendering their sensibility skills to be greatly diminished or they may even suffer from a complete loss of feelings in the lower extremities, and especially in the feet. The patient will often fail to notice or be aware when individual points of a foot are subjected to severe
5 constant pressure or repetitive stress, for example during long periods of standing or by use of badly fitting shoes, inducing the development of an pressure sore. Since metabolism is disturbed and blood circulation already can be reduced in diabetes patients, healing of such sores is most difficult.

Attempts have been made to prevent the development of pressure sores and
10 ulcers in a patient who might not be able to recognise presence of severe sore inducing condition.

Dressings with different kinds of indicators are known, e.g. from European Patent application No. 430 608 (E. R. Squibb & Sons, Inc.), which discloses a wound dressing comprising a temperature sensing liquid crystal tape, affixed to
15 the backing layer. A temperature change may indicate a change in wound condition. In the reference is also mentioned the possibility of a pressure indicator in the form of a piezoelectric element.

US Patent No. 5 642 096 (Paromed Medizintechnik GmbH) discloses a device for prevention of ulcers on the feet of diabetic patients. The device includes a
20 pressure and temperature sensor in the form of a piezoelectric element carried in the innersole of the shoe. The patient is warned by a signal, e.g. a buzz if the pressure reaches a critical level. The device is constricted to the innersole of the shoe, and does not cope with detecting impacts to other body parts e.g. the side of the foot or on hips or sacrum, and it is also technically complicated and
25 expensive.

Until now a dressing being capable of both handling wound exudate and at the same time relieving both static and dynamic pressure has not been disclosed.

It has now surprisingly been found that the above mentioned problem can be overcome by combining a shock-absorbing material with a moisture-absorbing

material rendering it possible to obtain an effective and durable dressing suitable for both wound healing and prophylaxis of pressure ulcers as well as for protection of fragile skin.

BRIEF DESCRIPTION OF THE INVENTION

- 5 The present invention relates to a pressure relieving dressing comprising an absorbent element and a substantially non-absorbing pressure distributing element.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is explained more in detail with reference to the drawings in which:

- 10 Figure 1 shows a top view of an embodiment of the invention.
Figure 2 shows another embodiment of the invention.
Figure 3 shows a cross-section of an embodiment of the invention.
Figure 4 shows a cross-section of another embodiment of the invention.
Figure 5 shows a cross-section of yet another embodiment of the invention.
15 Figure 6 shows a cross-section of a still further embodiment of the invention.
Figure 7 shows a cross-section of yet another embodiment of the invention.
Figure 8 shows a still further embodiment of the invention seen from above.

DETAILED DESCRIPTION OF THE INVENTION

- The invention relates to a pressure relieving dressing comprising an absorbent
20 element and a substantially non-absorbing pressure distributing element,
wherein the absorbent element constitutes a part of a proximal skin contacting
surface, said absorbent element being encircled by the pressure distributing
element constituting the remaining part of the surface of the dressing to be in
contact with the skin, characterised in that the absorbent element is situated
25 excentrically with respect to the pressure distributing element.

The absorbent element may be situated at the border of the pressure distributing element.

In order to prevent the development of ulcers and/or enhance the healing of ulcers a combination of an absorbent element and a pressure distributing and pressure shock-absorbing element has been shown to be advantageous. The absorbent element is able to handle exudates from a wound and provide the
5 optimal environment for wound healing, while the pressure distributing element will work as a shock absorber and a pressure distributing element and diminish further damage to the wound area.

By using a substantially non-absorbing pressure distributing element this will serve as a barrier to the wound exudate as well as the properties of the element
10 will not change due to absorption of wound exudate.

The dressing according to the present invention reduces the impacts from pressure shocks to the selected body part, and offers pressure distributing properties of susceptible areas. These properties are important both in the prophylactic phase as well as in the treatment of an ulcer or protection of the
15 former wound site after healing. The absorbent element of the dressing of the invention is preferably more compressible than the pressure distributing element covering the area next to the treated areas and in that way reducing the direct pressure on the wound.

The combination of an absorbent element combined with an pressure distributing
20 element ensures that no changes in properties of the dressing due to long term pressure is observed. The dressing of the invention can be in the form of a very flexible, thin device of a size rendering it suitable for wearing in shoes without discomfort.

The principles of pressure distributing is to transfer a (too) high pressure from a
25 high risk area to a larger area, preferably an area located proximal or bilateral to the threatened area.

This is often achieved by drawing a ring of pressure distributing material with the high risk area in the centre. However, by isolating the high risk area behind a heavy barrier of pressure distributing material, the high risk area will be locked up

inside the ring, giving rise to problems with the circulation of body fluids as well as a risk of developing oedemas. By placing the pressure distributing material apart from the centre of the device, e.g. with the shape of a horseshoe maybe with the legs of the shoe connected by a thin piece of pressure distributing

5 material, around the high risk area, a more open structure is achieved. The central piece of the horseshoe may preferably be in the end being first exposed to the pressure, e.g. if the dressing is worn on the heel, in the heel end, while the open end of the horseshoe is pointing towards the toes. In this way, the construction of the dressing may even enhance the circulation in the tissue of the

10 high risk area.

In one embodiment of the invention the dressing may be substantially planar with circular or elliptical shape for use on e.g. heels. The absorbent element may preferably be situated at the periphery of the dressing.

In another embodiment of the invention the dressing may be in the form of a

15 three-dimensional structure e.g. for use on toes.

The pressure distributing element is preferably an elastomer.

The pressure distributing element may comprise synthetic polymers such as silicones, polyurethanes, elastomeric copolymers or hydrophobic foams with designed properties or it may be a natural polymer such as natural rubbers.

20 The elastomer has great ability of distributing both the static pressure and the sudden impacts, and at the same time it is durable and does not collapse during use, but conserves its elasticity and shape.

Some elastomers are transparent, which may be an advantage when used in a dressing according to the invention. A transparent or semi-transparent dressing

25 will render it possible to watch the condition of the underlying skin or wound without removing the dressing.

In a preferred embodiment of the invention a water permeable elastomer is used, enabling water vapour transport through the dressing.

Foams are often used as pressure distributing materials. However, many foams may absorb liquid and change properties, by softening or even collapse.

- 5 It is preferred that the pressure distributing material does not significantly change pressure distributing properties when contacted with moisture or aqueous liquids, such as wound exudate and perspiration.

However, it may be advantageous to have a pressure distributing material being able to handle minor amounts of moisture. This can be achieved by incorporat-

- 10 ing an absorber in particular form in the pressure redistributing material.

In one embodiment of the invention the pressure distributing material comprises one or more indentations. The indentations may be in the form of holes, dots, ribs or the like. The presence of the indentations will provide more flexibility to the dressing and, depending on the depths of the indentations they may also

- 15 serve as diffusion points. The indentations may penetrate the pressure distributing material but not the top layer, if such is present.

Incorporation of a support material in the bandage may be advantageous. It may be in the form of a web or net, e.g. a non-woven or a nylon net. The support material may e.g. be situated at the proximal side of the dressing.

- 20 The product may be used both as an ulcer prophylaxis and as a wound dressing for all kinds of pressure ulcers, such as foot ulcers, leg ulcers, hip ulcers and sacrum ulcers. The dressing may also be used as a protection of recently healed and thus still fragile skin.

- The absorbent element may comprise a hydrophilic foam, such as polyurethane,
25 silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or a water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinyl-pyrrolidone gels or hydrocolloids.

Preferably the absorbent element is more compressible than the pressure distributing element.

- The absorbent element may be located as discrete or connected zones in the pressure distributing element, either penetrating the pressure distributing
5 element from top side to the skin-contacting side of the element or only going partly through the dressing, with the open end towards the skin.

The absorbent element may be in the form of a pattern of interconnected zones.

The zones of the absorbent element may be of any shape, e.g. in the form of dots, lines, squares or concentric circles.

- 10 The absorbent element is preferably situated excentrically with respect to the pressure distributing element.

- In an embodiment of the invention the absorbent element may comprise more than one absorber, e.g. a foam part in the portion in contact with the skin, and on top of the foam a super absorber part being capable of soaking the moisture
15 from the foam and in this way remove excess moisture from the skin-contacting part.

It is preferred that the surface of the dressing to be brought in contact with the skin shows adhesive properties.

- The device can be fully or partly covered with an adhesive on the skin-facing
20 surface in order to attach the device to the wearers body-part, e.g. the plantar, heel or toes. Alternatively, the adhesive can be located on the non-skin facing side, and in this way attach the device to the innersole of the wearers shoe.

The adhesive may be coated to the surface of the dressing in the form of a pattern, such as dots or lines.

In one embodiment the pressure distributing element has inherent adhesive properties.

The device may be covered on the non-skin-contacting surface with a top layer, e.g. a foam, a non-woven, or a film, such as a polyurethane film. The layer will
5 enhance the strength of the dressing as well as it may serve as a barrier for the wound exudate. Further, the top layer may reduce the friction of the dressing.

In one embodiment of the invention the top layer extends beyond the edge of the pressure distributing element defining a flange around the dressing. The flange may optionally be covered with an adhesive.

- 10 The dressing may also comprise a protective cover or release liner. It does not need to have the same contour as the dressing, e.g. a number of dressings may be attached to a larger sheet of protective cover. The protective cover is not present during the use of the dressing of the invention and is therefore not an essential part of the invention.
- 15 In one embodiment of the invention the dressing further comprises a pressure indicator. The pressure indicator may be visible from the distal side of the dressing, when in use, said pressure indicator showing a durable change after having been exposed to a pressure above a defined level.

The indicator may be dispersed in an adhesive.

- 20 In one embodiment of the invention the indicator is incorporated in a film.

The indicator is preferably capable of producing a colour change. Alternatively, the indicator may create a visible change by changing solubility, and in this way change form e.g. clear to opaque.

- In another embodiment of the invention the indicator may be in the form of a
25 pressure indicating film, preferably in the form of a mono- or bilayer film.

The indicator may be in the form of microcapsules. These microcapsules may be coated on the dressing or a film or they may be homogeneously dispersed as discrete particles in a matrix, such as an adhesive, absorbent or pressure distributing element.

- 5 The incorporation of a pressure indicator renders it possible for the patient or the health care person, to monitor the points of critical pressure in the area around the wound without removing the dressing.

The pressure indicator may be provided in a form either having gradual pressure indication properties or the indicator may have a critical pressure level, above
10 which the indicator will develop a visual indication.

Furthermore, the dressing of the invention may comprise a "non touch" grip known per se for applying the dressing to the skin without touching the adhesive layer. Such a non-touch grip is not present after application of the dressing.

- The dressing according to the invention may comprise wound healing associated
15 indicator(s) such as indicators of pH, partial pressure of O₂, temperature, radical mechanisms or biotechnological assays, e.g. indicating formation of collagen.

It is also advantageous that a dressing according to the invention comprises wound healing associated indicator(s) or similar device for treatment or prophylaxis of formation of wounds and/or skin abnormalities.

- 20 This opens for a combined medical treatment of the wound and an easy and sterile application of the active ingredients, e.g. by incorporating active ingredients such as a cytokine such as growth hormone or a polypeptide growth factor giving rise to the incorporation of such active substances in a form being apt to local application in a wound in which the medicament may exercise its effect on
25 the wound, other medicaments such as bacteriostatic or bactericidal compounds, e.g. iodine, iodopovidone complexes, chloramine, chlorohexidine, silver salts such as sulphadiazine, silver nitrate, silver acetate, silver lactate, silver sulphate, silver-sodium-thiosulphate or silver chloride, zinc or salts thereof, metronidazol,

- aulpha drugs, and penicillins, tissue-healing enhancing agents, e.g. RGD tripeptides and the like, proteins, amino acids such as taurine, vitamins such ascorbic acid, enzymes for cleansing of wounds, e.g. pepsin, trypsin and the like, proteinase inhibitors or metalloproteinase inhibitors such as Illostat or ethylene
- 5 diamine tetraacetic acid, cytotoxic agents and proliferation inhibitors for use in for example surgical insertion of the product in cancer tissue and/or other therapeutic agents which optionally may be used for topical application, pain relieving agents such as lidocaine or chinchocaine, emollients, retinoids or agents having a cooling effect which is also considered an aspect of the invention.
- 10 The invention also relates to the use of a dressing comprising a pressure indicator being visible from the distal side of the dressing, when in use for indicating a critical pressure impact to a body part.

The invention relates further to a method of indicating a critical pressure level to a body part, comprising applying a dressing comprising a pressure indicator

- 15 being visible from the distal side of the dressing, when in use, and after a period of use, inspecting the dressing and detecting an indication of critical pressure.

DETAILED DESCRIPTION OF THE DRAWINGS

An embodiment of the invention is shown in Figure 1. In this embodiment, a zone of absorbent material (1) surrounded by a pressure distributing material (2). A

- 20 pressure indicator may be homogeneously dispersed in the pressure distributing material.

- In Figure 2 is shown a preferred embodiment of the invention, with a zone of absorbent material (1) and a pressure distributing element (2). In this embodiment the absorbent material is located near the edge of the dressing. By placing
- 25 the pressure distributing material here a more open structure is achieved. When applied to the plantar of the foot with the absorbent element pointing towards the toes, the large zone of the pressure distributing element will be the first zone to be exposed to pressure.

In Figure 3 is shown a cross-section of an embodiment of the invention, with a zone of absorbent element (1) and a pressure distributing element (2). The absorbent element extends partly through the pressure distributing element. On the distal side of the absorbent element is a pressure indicating film (8). The edges of the dressing are bevelled or rounded to enhance the comfort for the user.

In Figure 4 is shown another embodiment of the invention in which the surface of the dressing not contacted with the skin is covered by a top layer (3). The top layer (3) may enhance the mechanical strength of the dressing. The top layer may be a pressure indicating film. The absorbent element (1) extends through the pressure distributing element (2).

In Figure 5 is shown a cross-section of the same embodiment of the invention with one absorbent element (1) at the skin-contacting surface, and on top of the absorbent element is a super absorber (4). A top layer (3) is covering the non-skin-facing surface of the dressing. The top layer may comprise a pressure indicator.

In Figure 6 is shown another embodiment of the invention in which the edges are not bevelled, with a top layer (3) on one side and a layer of an adhesive (5) on the skin-facing side. A pressure indicator may be homogeneously dispersed as discrete particles in the adhesive (5).

Figure 7 is showing an embodiment of the invention in which the top layer (3) is elongated to extend beyond the pressure distributing element (2). On the elongated part of the layer (6) an adhesive (7) is applied, essentially making the concept an island dressing, with an adhesive flange and a non-adhesive centre part. A pressure indicator may be incorporated in the top layer, pressure distributing element or absorbent element.

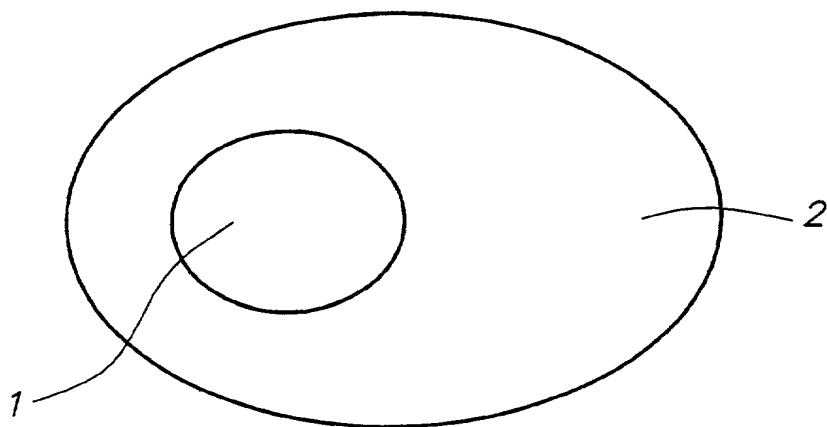
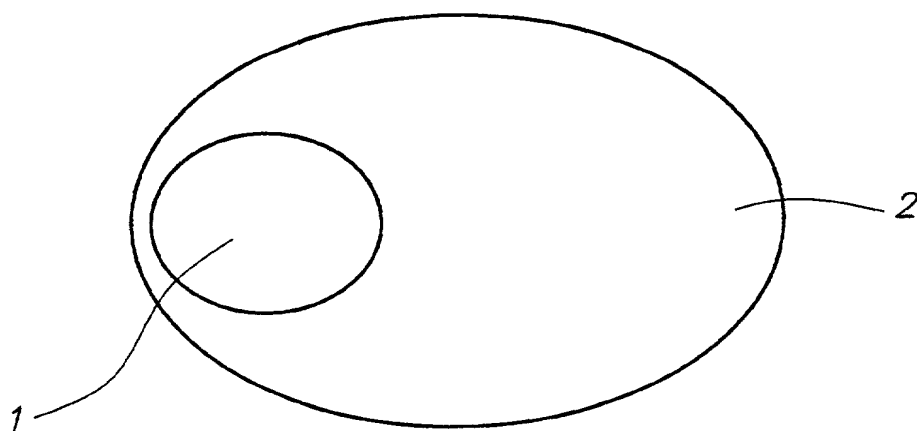
In Figure 8 is shown an embodiment of the invention, with a zone of absorbent material (1) and a pressure distributing element (2). Like in Figure 2, the absorbent material is located near the edge of the dressing. Indentations (9) in the form

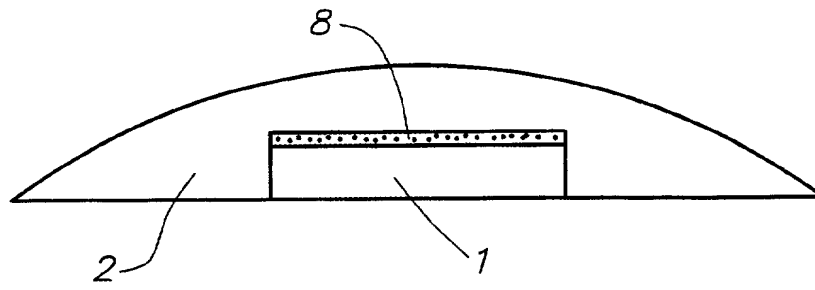
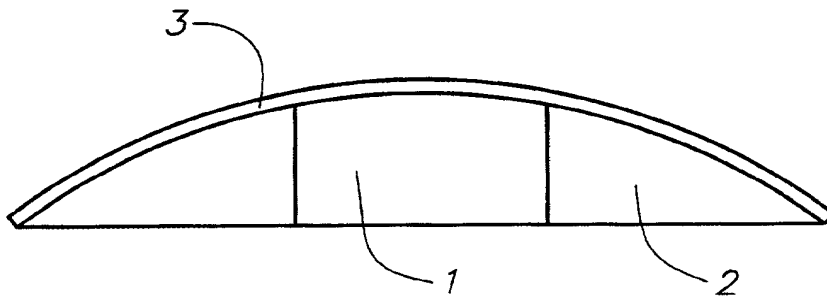
5 such is present.

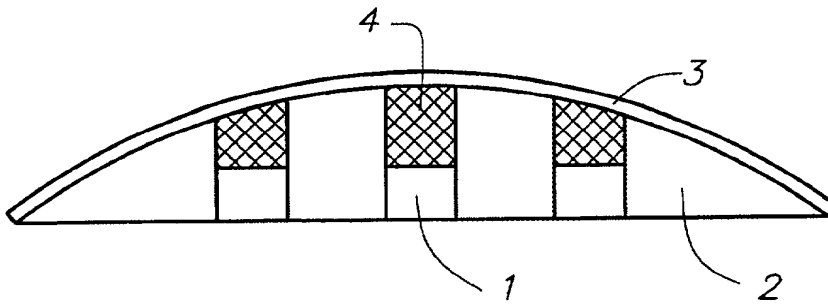
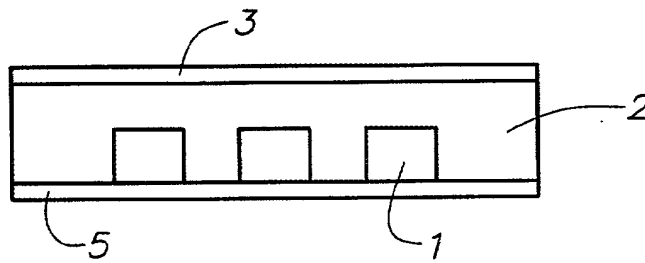
CLAIMS

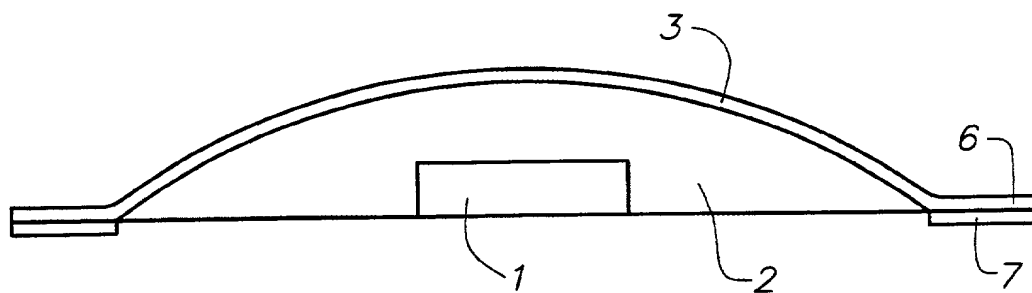
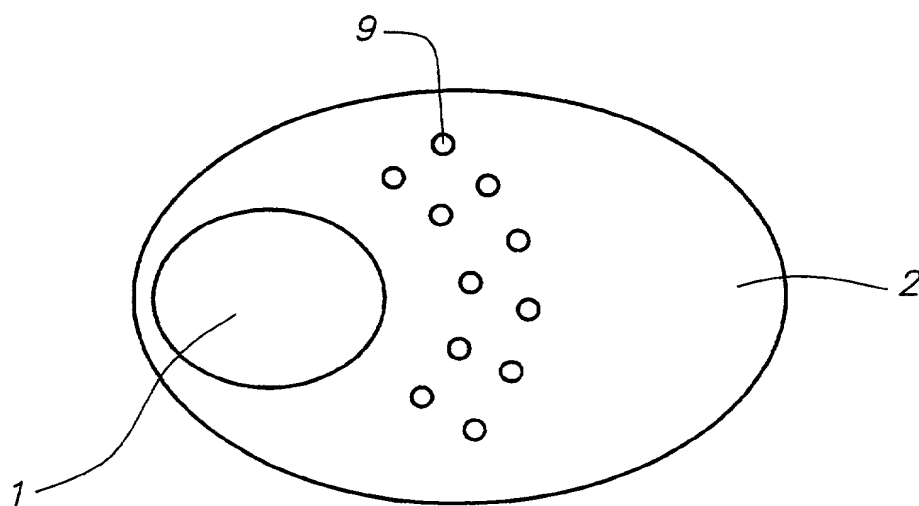
1. A pressure relieving dressing comprising an absorbent element (1) and a substantially non-absorbing pressure distributing element (2), wherein the absorbent element (1) constitutes a part of a proximal skin contacting surface,
- 5 said absorbent element (1) being encircled by the pressure distributing element (2) constituting the remaining part of the surface of the dressing to be in contact with the skin, characterised in that the absorbent element (1) is situated excentrically with respect to the pressure distributing element (2).
2. A dressing according to claim 1 characterised in that the absorbent element
- 10 (1) is situated at the border of the pressure distributing element (2).
3. A dressing according to claim 1 or 2, characterised in that the pressure distributing element (2) is an elastomer.
4. A dressing according to claim 3, characterised in that the elastomer comprises a synthetic polymers such as silicones, polyurethanes, elastomeric copolymers
- 15 or hydrophobic foams with designed properties or is a natural polymer such as natural rubber.
5. A dressing according to any of claims 1-4, characterised in that the absorbent element (1) comprises a hydrophilic foam, such as polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or water
- 20 soluble or gelling biopolymers such as polysaccharides. e.g. alginates, polyvinylpyrrolidone gels or hydrocolloids.
6. A dressing according to any of claims 1-5, characterised in that the surface opposite the skin-contacting surface of the dressing is covered by a top layer (3).
7. A dressing according to any of claims 1-6, characterised in that the absorbent
- 25 element (1) extends through the pressure distributing element (2).
8. A dressing according to any of claims 1-6, characterised in that the absorbent element (1) extend partly through the pressure distributing element (2).

9. A dressing according to any of claims 1-8, characterised in that the pressure redistributing material (2) comprises one or more indentations (9).
10. A dressing according to any of claims 1-9, characterised in that the dressing comprises a pressure indicator.
- 5 11. A dressing according to any of claims 1-10, characterised in that the absorbent element (1) comprises a pharmaceutical or antimicrobial agent.
12. A dressing according to any of claims 1-11, characterised in that the surface of the dressing to be brought in contact with the skin shows adhesive properties.

*Fig. 1**Fig. 2*

*Fig. 3**Fig. 4*

*Fig. 5**Fig. 6*

*Fig. 7**Fig. 8*

DECLARATION AND POWER OF ATTORNEY U.S.A.

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P87157US0

ALL PATENTS, INCLUDING DESIGN
OR APPLICATION BASED ON PCT, PARIS CONVENTION;
ON PRIORITY; OR PROVISIONAL APPLICATIONS

As a below named inventor, I declare that my residence, postal office address and citizenship are stated below next to my name, the information given herein is true, that I believe that I am the original, first and sole inventor (if only one name is listed at 201 below), or an original, first and joint inventor (if plural inventors are named below at 201-203, or on additional sheets attached hereto) of the subject matter which is claimed and for which patent is sought on the invention entitled:

A PRESSURE RELIEVING DRESSING

which is described and claimed in: ☒ PCT International Application No. PCT/DK99009105 filed April 8, 1999
☐ the attached specification ☐ the specification in application Serial No. _____ filed _____
(If applicable) and amended on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56. I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

PA 1989 00463 (Number)	DENMARK (Country)	7 April 1999 (Day/Month/Year Filed)
PA 1989 00464 (Number)	DENMARK (Country)	7 April 1999 (Day/Month/Year Filed)
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)

Priority Claimed

<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

Application No. _____ Filing Date _____ Application No. _____ Filing Date _____

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which becomes available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)

(Filing Date)

(Status: patented, pending, abandoned)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorneys (Registration No.) to prosecute this application, receive and act on instructions from my agent and transact all business in the Patent and Trademark Office connected therewith. HARVEY B. JACOBSON, JR. (20,851); JOHN CLARKE HOLMAN (22,789); MARVIN R. STERN (20,849); ALLEN S. MELSER (27,215); MICHAEL R. SLOBASKY (28,421); JONATHAN L. SCHERER (29,851); IRWIN M. AISENBERG (19,007); WILLIAM E. PLAYER (31,408); DON S. HAM (45,307) and NATHANIEL A. HUMPHRIES (22,772)

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			ZIP CODE <u>2750</u>
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RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY
			ZIP CODE

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201 <u>Truls Steen Larsen</u>	SIGNATURE OF INVENTOR 202 <u>Henrik Olsen</u>	SIGNATURE OF INVENTOR 203
DATE <u>25/9 2001</u>	DATE <u>25/9 2001</u>	DATE

Additional inventors are named on separately numbered sheets attached hereto.

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